K000696

ADMINISTRATIVE INFORMATION

OCT 1 9 2000

Manufacturer Name: MacroPore, Inc.
6740 Top Gun Street
San Diego, CA 92121

Official Contact: Kenneth K. Kleinhenz
Director of Regulatory Affairs
Telephone (858) 458-0900
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DEVICE NAME

Classification Name: Plate, Bone

Trade/Proprietary Name: MacroPore*MX* Mandibular Fixation System

ESTABLISHMENT REGISTRATION NUMBER

2031733

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 872.4760 Bone Plates are classified as Class II. Bone Plates have been assigned Product Code JEY.

INTENDED USE

MacroPore*MX* Mandibular Fixation System is used to stabilize fractured bones in the mandible when used in conjunction with appropriate maxillomandibular fixation (MMF). The system utilizes a double plating technique across the fracture line where one plate is placed superior and the other plate is placed in the inferior region of the mandibular bone.

DEVICE DESCRIPTION

Design Characteristics

MacroPore*MX* Mandibular Fixation System is composed of resorbable plates and 2.7 mm resorbable screws manufactured from poly (L-lactide-co-D,L-lactide) 70:30 (PLA). MacroPore*MX* Mandibular Fixation System is provided in various shapes and sizes and will be provided in larger sizes as needed for particular surgical procedures.

Material Composition

MacroPore*MX* Mandibular Fixation System is fabricated from polylactic acid.

In Vitro Testing

Characterization of the effects on inherent viscosity when the raw material is processed into the MacroPore*MX* Mandibular Fixation System verifies the amorphous nature of the MacroPore*MX* Mandibular Fixation System. Important properties of the material, such as inherent viscosity and the amorphous nature of the material, are preserved and not significantly effected by the manufacturing process. The processing of the material also determined that there was no significant lot-to-lot variation in the product's inherent viscosity when different lots of raw material are utilized.

Because the MacroPore*MX* Mandibular Fixation System is intended to be heated in the surgical suite to temperatures above the material's glass transition temperature to facilitate shaping to anatomic structures, testing was performed to determine the effect of prolonged heating in saline at 60°C on inherent viscosity. The testing demonstrates that viscosity stayed within an appropriate range over 120 minutes. Therefore, the relatively brief exposure anticipated during the surgical preparation of the MacroPore*MX* Mandibular Fixation System is not expected to have a significant effect on its mechanical properties.

Accelerated aging testing was performed on MacroPore*MX* Mandibular Fixation System. Simulated *in vivo* accelerated testing indicates that the MacroPore*MX* Mandible Fixation System retains all of its strength for the first 9 months and a steadily decrease in strength to zero after approximately 18 months.

EQUIVALENCE TO MARKETED PRODUCT

MacroPore*MX* Mandibular Fixation System shares indications and design principles with the predicate device which has been determined by FDA to be substantially equivalent to a pre-amendment device.

Indications For Use

The MacroPore*MX* Mandibular Fixation System is indicated for the same uses and anatomical regions as the predicate device. Both the MacroPore*MX* Mandibular Fixation System and the predicate device are indicated for fixating fractures of the jaw. The MacroPore*MX* Mandibular Fixation System intends to utilize a substantially equivalent indications for use statement that was cleared by FDA for the predicate device. The MacroPore*MX* Mandibular Fixation System is used to stabilize fractured bones in the mandible when used in conjunction with appropriate maxillomandibular fixation (MMF). The system utilizes a double plating technique across the fracture line where one plate is placed superior and the other plate is placed in the inferior region of the mandibular bone.

Design and Materials

The physical design and functional characteristics of the MacroPore*MX* Mandibular Fixation System and the predicate device are substantially equivalent. Both the predicate device and the MacroPore*MX* Mandibular Fixation System have similar plate design features with substantially equivalent shapes, sizes, and dimensions. The mechanical characteristics of the MacroPore*MX* Mandibular Fixation System are also substantially equivalent to the predicate device. The titanium device differs from MacroPore*MX* Mandibular Fixation System device in that it may be left in place permanently or must be removed surgically, whereas the polymer devices are intended to be metabolized by the body and do not require removal.

SUMMARY : TABLE OF SUBSTANTIAL EQUIVALENCE

The MacroPore*MX* Mandibular Fixation System and Walter Lorenz Titanium Mini Bone Plates and Screws are substantially equivalent in the following aspects:

	Subject Device	Predicate Device	Related Device	
	MacroPore*MX* Mandibular Fixation System	**Walter Lorenz Titanium Mini Bone Plates and Screws**	**MacroPore Protective Sheet (Protego System) (K972913)**	**2.5mm LactoSorb Screws (K981666)**
Intended Use	The MacroPoreMX Mandibular Fixation System is used to stabilize fractured bones in the mandible when used in conjunction with appropriate maxillomandibular fixation (MMF). The system utilizes a double plating technique across the fracture line where one plate is placed superior and the other plate is placed in the inferior region of the mandibular bone.	The titanium mini bone plates and screws are used to stabilize fractures bones in the jaw. It is made of pure titanium and conforms to industry standards such as ASTM.	MacroPore Protective Sheet is intended for use in trauma and reconstructive procedures in the midface and craniofacial skeleton: 1. Comminuted fractures of the naso-ethmoidal and infraorbital areas 2. Comminuted fractures of the frontal sinus wall 3. Trauma of the midface or craniofacial skeleton 4. Reconstructive procedures of the midface or craniofacial skeleton. The system is not intended for use in the mandible and/or for full load bearing procedures.	The 2.5mm LactoSorb Screws are indicated for use as fixation in mandibular osteotomy procedures, including but not limited to: • Sagittal split osteotomy • Vertical Ramus osteotomy • Inferior border osteotomy • Subapical osteotomy • Genioplasty
Design	Resorbable plates and screws of various shapes and sizes	2.0 mm plates and screws of various shapes and sizes.	Plates, screws and tacks of various sizes.	Resorbable screws provided in various lengths
Material	Poly (L-lactide-co-D,L-lactide) 70:30, amorphous	100% titanium	Poly (L-lactide-co-D,L-lactide) 70:30, amorphous	82% PLA/ 18% PGA
Product Code	JEY	JEY	HRS and HWC	DZL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2000

Mr. Kenneth K. Kleinhenz
Director of Regulatory Affairs
MacroPore, Incorporated
6740 Top Gun Street
San Diego, California 92121

Re: K000696
Trade Name: MacroPoreMX Mandibular Fixation System
Regulatory Class: II
Product Code: JEY
Dated: July 24, 2000
Received: July 26, 2000

Dear Mr. Kleinhenz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4296. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000696

Device Name: **MacroPore*MX* Mandibular Fixation System**

Indications for Use:
MacroPore*MX* Mandibular Fixation System is used to stabilize fractured bones in the mandible when used in conjunction with appropriate maxillomandibular fixation (MMF). The system utilizes a double plating technique across the fracture line where one plate is placed superior and the other plate is placed in the inferior region of the mandibular bone.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000696